

Food and Drug Administration, HHS

§ 880.6991

straps. The frame may be fixed or collapsible for use in an ambulance.

(b) *Classification*. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 880.9.

[45 FR 69682, Oct. 21, 1980, as amended at 63 FR 59229, Nov. 3, 1998]

§ 880.6920 Syringe needle introducer.

(a) *Identification*. A syringe needle introducer is a device that uses a spring-loaded mechanism to drive a hypodermic needle into a patient to a predetermined depth below the skin surface.

(b) *Classification*. Class II (performance standards).

§ 880.6960 Irrigating syringe.

(a) *Identification*. An irrigating syringe is a device intended for medical purposes that consists of a bulb or a piston syringe with an integral or a detachable tube. The device is used to irrigate, withdraw fluid from, or instill fluid into, a body cavity or wound.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. If the device is not labeled or otherwise represented as sterile, it is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[45 FR 69682, Oct. 21, 1980, as amended at 66 FR 38807, July 25, 2001]

§ 880.6970 Liquid crystal vein locator.

(a) *Identification*. A liquid crystal vein locator is a device used to indicate the location of a vein by revealing variations in the surface temperature of the skin by displaying the color changes of heat sensitive liquid crystals (cholesteric esters).

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in

subpart E of part 807 of this chapter, subject to the limitations in § 880.9.

[45 FR 69682, Oct. 21, 1980, as amended at 54 FR 25050, June 12, 1989; 66 FR 38807, July 25, 2001]

§ 880.6980 Vein stabilizer.

(a) *Identification*. A vein stabilizer is a device consisting of a flat piece of plastic with two noninvasive prongs. The device is placed on the skin so that the prongs are on either side of a vein and hold it stable while a hypodermic needle is inserted into the vein.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. If the device is not labeled or otherwise represented as sterile, it is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[45 FR 69682, Oct. 21, 1980, as amended at 66 FR 38807, July 25, 2001]

§ 880.6990 Infusion stand.

(a) *Identification*. The infusion stand is a stationary or movable stand intended to hold infusion liquids, infusion accessories, and other medical devices.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 880.9.

[63 FR 59718, Nov. 5, 1998]

§ 880.6991 Medical washer.

(a) *Identification*. A medical washer is a device that is intended for general medical purposes to clean and dry surgical instruments, anesthesia equipment, hollowware, and other medical devices.

(b) *Classification*. Class II (special controls). The special control for this device is the FDA guidance document entitled "Class II Special Controls Guidance Document: Medical Washers and Medical Washer-Disinfectors." The device is exempt from the premarket

§ 880.6992

notification procedures in subpart E of part 807 of this chapter subject to § 880.9.

[67 FR 69121, Nov. 15, 2002]

§ 880.6992 Medical washer-disinfector.

(a) *Identification.* A medical washer-disinfector is a device that is intended for general medical purposes to clean, decontaminate, disinfect, and dry surgical instruments, anesthesia equipment, hollowware, and other medical devices.

(b) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled “Class II Special Controls Guidance Document: Medical Washers and Medical Washer-Disinfectors.”

(1) Medical washer-disinfectors that are intended to clean, high level disinfect, and dry surgical instruments, anesthesia equipment, hollowware, and other medical devices.

(2) Medical washer-disinfectors that are intended to clean, low or intermediate level disinfect, and dry surgical instruments, anesthesia equipment, hollowware, and other medical devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 880.9.

[67 FR 69121, Nov. 15, 2002]

PART 882—NEUROLOGICAL DEVICES

Subpart A—General Provisions

Sec.

882.1 Scope.

882.3 Effective dates of requirement for premarket approval.

882.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

Subpart B—Neurological Diagnostic Devices

882.1020 Rigidity analyzer.

882.1030 Ataxiagraph.

882.1200 Two-point discriminator.

882.1240 Echoencephalograph.

882.1275 Electroconductive media.

882.1310 Cortical electrode.

882.1320 Cutaneous electrode.

882.1330 Depth electrode.

882.1340 Nasopharyngeal electrode.

882.1350 Needle electrode.

21 CFR Ch. I (4–1–13 Edition)

882.1400 Electroencephalograph.

882.1410 Electroencephalograph electrode/lead tester.

882.1420 Electroencephalogram (EEG) signal spectrum analyzer.

882.1430 Electroencephalograph test signal generator.

882.1460 Nystagmograph.

882.1480 Neurological endoscope.

882.1500 Esthesiometer.

882.1525 Tuning fork.

882.1540 Galvanic skin response measurement device.

882.1550 Nerve conduction velocity measurement device.

882.1560 Skin potential measurement device.

882.1570 Powered direct-contact temperature measurement device.

882.1610 Alpha monitor.

882.1620 Intracranial pressure monitoring device.

882.1700 Percussor.

882.1750 Pinwheel.

882.1790 Ocular plethysmograph.

882.1825 Rheoencephalograph.

882.1835 Physiological signal amplifier.

882.1845 Physiological signal conditioner.

882.1855 Electroencephalogram (EEG) telemetry system.

882.1870 Evoked response electrical stimulator.

882.1880 Evoked response mechanical stimulator.

882.1890 Evoked response photic stimulator.

882.1900 Evoked response auditory stimulator.

882.1925 Ultrasonic scanner calibration test block.

882.1935 Near Infrared (NIR) Brain Hematoma Detector.

882.1950 Tremor transducer.

Subparts C–D [Reserved]

Subpart E—Neurological Surgical Devices

882.4030 Skull plate anvil.

882.4060 Ventricular cannula.

882.4100 Ventricular catheter.

882.4125 Neurosurgical chair.

882.4150 Scalp clip.

882.4175 Aneurysm clip applier.

882.4190 Clip forming/cutting instrument.

882.4200 Clip removal instrument.

882.4215 Clip rack.

882.4250 Cryogenic surgical device.

882.4275 Dowel cutting instrument.

882.4300 Manual cranial drills, burrs, trephines, and their accessories.

882.4305 Powered compound cranial drills, burrs, trephines, and their accessories.

882.4310 Powered simple cranial drills, burrs, trephines, and their accessories.

882.4325 Cranial drill handpiece (brace).

882.4360 Electric cranial drill motor.

882.4370 Pneumatic cranial drill motor.